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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------------------------------------------------------|-------------|----------------------|------------------------------|------------------|
| 09/745,751 | 12/21/2000 | Mark N. Hochman | 3486-018 | 1104 |
| 22440 7590 01/21/2005 GOTTLIEB RACKMAN & REISMAN PC 270 MADISON AVENUE 8TH FLOOR NEW YORK, NY 100160601 | | | EXAMINER HAYES, MICHAEL J | |
| | | | ART UNIT 3763 | PAPER NUMBER |

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/745,751 | | HOCHMAN, MARK N. | |
| | Examiner | | Art Unit | |
| | Michael J. Hayes | | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-23 is/are pending in the application.
- 4a) Of the above claim(s) 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species 2, claims 1, 3-11 in Paper No. 6 (received 4/21/03) is acknowledged.

Newly submitted claims 14-23 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly submitted claims are drawn to a method of eliminating pain during drug administration, whereas the originally examined claims are drawn to a method of advancing a needle into tissue with simultaneous rotation to reduce needle deflection. The claims are subcombinations usable together.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 1, 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitations added to the claims reciting a method of painless administration of a drug or preventing pain-producing deflection of a needle during advancement through tissue

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is new matter not originally disclosed in the specification as filed. The original specification mentions a method whereby "the amount of pain felt by the patient may be reduced." (abstract). This mention of a possibility to reduce pain does not provide a description of a method preventing pain.

Claims 1, 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's recitation of a painless method of administering a drug or a method that prevents pain-producing needle deflection is not enabled because Applicant has not provided a disclosure to enable one skilled in the art to use the method to provide painless needle deflection (or even reduced pain needle deflection) without undue experimentation. The claims are broadly recited with limitations to advancing a needle with simultaneous rotation to prevent pain from needle deflection. There is no description of the amount of deflection to avoid in order to prevent pain from any remaining deflection. The state of the prior art does not provide information in providing painless needle advancement so this is not an instance of Applicant not teaching what is well known in the art. The level of predictability in the art is very low because the subject matter is subjective pain in biological systems. Applicant has not provided any direction or working examples concerning the elimination of pain in advancing needles with reduced deflection. The quantity of experimentation would be large because of the biological variability and subjective nature of pain measurements. Because of these factors the examiner concludes that the method of painless needle advancement with reduced deflection, as recited in the claims is not enabled.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by BROWN (U.S. Patent No. 3,244,172). Brown discloses that it is well known in the art to turn or twist a needle of a syringe while inserting it through tissue in methods of injecting. (1:15-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 6, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over KUHLE (US Patent No. 5,938,635) in view of Violante (US Patent No. 6,106,473). Kuhle discloses a method of advancing a needle while rotating to reduce deflection of the needle. Kuhle teaches a rotation of 360 degrees to balance forces, or alternatively several rotations of 180 degrees while advancing the needle. Kuhle discloses his method with a biopsy needle and

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does not discuss injecting a drug. Violante teaches the importance in the medical arts of placing needles and other medical devices for biopsy and drug delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Violante in the method of Kuhle to recognize the desirability for accurately placing biopsy and drug delivery needles and the established equivalence between placing needles used for biopsy and placing drug delivery needles in identifiable locations. Re claim 6 use of an advance rate of 2-4 mm/sec would be obvious to one of ordinary skill in the art as a design choice because Applicant has not stated that this advance rate serves any particular purpose or solves any stated problem and it appears that other advance rates would function equally as well. Applicant has not established any criticality to this advance rate.

Claims 3, 4, 8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over KUHLE and VIOLANTE as applied to claims 1 and 7 above, and further in view of Garnier (US Patent No. 4381777). Kuhle and Violante disclose the claimed invention except for rotating the needle in one direction, then the opposite direction. Violante teaches one directional and also bi-directional rotation (1:22-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Violante in the method of Kuhle and Garnier in order to avoid special precautions (i.e., achieve a simpler method) and to avoid injury or breakage.

Response to Arguments

It is noted that Applicant agrees that Brown discloses “the usual procedure is to insert the needle by a sharp jab or pushing action” and that “a turning or twisting action may be employed to cause the needle to enter the tissue more easily or more easily affect removal.” (remarks

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received 9/3/04, pg. 8). Applicant argues that this disclosure does not mean the needle is rotated and translated simultaneously. The examiner disagrees and reads the disclosure with its plain meaning that the needle is advanced into tissue with a turning action to use less force in making the needle to enter the tissue more easily. Applicant remarks concerning lack of pain management in the prior art are not convincing because if turning and advancing a needle eliminates pain, as newly put forth by Applicant, then the prior art inherently does also.

Applicant generally argues that Kuhle or Garnier is not relevant to pain management. The examiner maintains the rejection because the prior art need not recognize inherent properties.

Applicant points out that Kuhle discloses a straight trajectory by rotating a needle while translating it (remarks received 9/3/04, pg. 8), but that this does not limit needle deflection. The examiner disagrees because straight trajectory would limit deflection (i.e., rotating the needle in the prior art limits the deflection over non-rotating translation).

In regards to claim 6, Applicant feels that the examiner has rejected the claim because of a determination of non-importance. The Applicant appears to be confusing importance with obviousness. All limitations are important to the inventions as claimed; however, importance does not mean non-obviousness. Applicant has not established the criticality of using an advancing rate of 2-4mm/sec. Applicant's remarks concerning uniform or constant advancement is irrelevant because a consistent or uniform advancement rate is not disclosed by Applicant in the application as filed, and would be new matter if introduced at this stage of prosecution.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
12 January 2005



**MICHAEL J. HAYES
PRIMARY EXAMINER**